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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,216	08/11/2000	Scott J Hultgren	WSHU2005.1	7884

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SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

SHEINBERG, MONIKA B

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/30/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/637,216

Applicant(s)

HULTGREN ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) 4-11,14,16,17 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,12,13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4-17 and 19-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant is requested to amend the claims to reflect the elected Group I (claims 1-21); peptide as according to Formula I comprising SEQ ID No: 12 which is a mimic of an amino terminal motif of a pilus subunit that has antibacterial activity against the Gram-negative bacterium *Escherichia coli* as per the election in applicants response filed 20 June 2001.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 4-11, 14, 16, 17 and 19-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Sequence Non-Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because Figures 3B, 3C and 8A contain amino acid sequences. A Sequence Listing and a computer readable format of it must be provided with a statement that the two are identical. The sequence presented in the figure must still be included in the Sequence Listing; and a sequence identifier (SEQ ID NO: X) must be used, either in the drawing or in the Brief Description of the Drawings. Due to the approval of the drawings, applicant is requested to make the amendment to the Description of the Drawings to include the sequence identifiers. Applicant is reminded that CD-ROM sequence listings are now accepted instead of a paper copy of the sequence listing for the specification. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance. Failure to comply may result in abandonment of this application.

Response to Amendment B

Applicants' arguments, filed 8 July 2002, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 12, 13 and 15 are rejected under 35 U.S.C. 103 (a) as being obvious over Marklund et al. in view of Kuehn et al. (*Science*, 1993).

This rejection is maintained and reiterated from the previous action mailed 13 September 2001. Applicant argues that Marklund et al does not disclose a mimic having the claimed features of the isolated compound, nor all the limitations of the claims. However the elected sequence, SEQ ID No: 12 (of papK), follows the rules set by the indicated Formula 1 that is further limited by claim 13. Since the sequence elected is publicly known (Marklund et al. has the following peptide, SEQ ID No: 12 entered into an NIH database as accession #: S16400) and Kuehn et al teaches the method steps as claimed with synthetic peptides, it would be obvious for

one of ordinary skill in the art to isolate the known sequence or make a synthetic peptide of the known sequence, and modify the method taught by Kuehn et al to include the analysis with SEQ ID No: 12. Kuehn et al teaches that papK inhibits the papD chaperone. The detailing of the analysis is concentrated upon the carboxyl terminus sequence of the papG pilus subunit, however papK is included within the analysis performed on all the pilus subunits. In addition, Kuehn et al indicates, on page 1239, that other regions "such as NH2-terminal sequence in the pilus subunits" (last column, last paragraph) can be involved in chaperone binding. The sequence of peptide being known, will still bind to the correlating amino acids disregarding amino or carboxyl termini. Pilus assembly inhibition by designing synthetic peptides is motivated by the summary in the reference on page 1240 (last paragraph):

... the mode of chaperone binding described in this article actually presents a "snapshot" of a process fundamental to Gram-negative pathogens. The molecular details of the charperone-adhesin interaction and optimization... may lead to the design of high affinity synthetic inhibitors which would prevent pilus assembly...

Kuehn et al further demonstrates designing related and binding of "pilus-subunit-related peptides" (p.1236, legend of Figure 2) blocks complex formation for pilus assembly thus indicating a degree of success in using pilus subunit-related peptide (as is SEQ ID No: 12) to inhibit pilus assembly.

Applicant is reminded that under U.S. Patent Law: "a claim in a patent application directed to an old compound in the art does not become patentable merely by measuring a new characteristic thereof", such as the claimed pilus assembly inhibition. As such any claims that are drawn to the practice of SEQ ID No: 12 are rejected.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicants also argue that Kuehn et al does not teach the binding of the compound to a pilus subunit groove. However claim 1 only requires that the isolated compound or peptide

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"inhibits pilus assembly" (line 2) thus the limitation is not required to be demonstrated by the reference. Therefore, the arguments are non-persuasive to overcome the rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Inquiries


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 29, 2002
Monika B. Sheinberg
Art Unit 1631

MBS


ARDIN H. MARSCHEL
PRIMARY EXAMINER